



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

AUG 14 2000

The Honorable Dan Burton
Chairman, Committee on Government Reform
and Oversight
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letters regarding concerns that have been raised relative to any potential association between autism and certain vaccines. I apologize for the delay in responding.

The Department of Health and Human Services (HHS) is committed to the careful investigation of all vaccine safety issues, and in this regard, we are negotiating a contract with the Institute of Medicine (IOM) to create a standing IOM Immunization Review Panel that will meet at least three times per year to address topics of public concern as they arise about the safety of vaccines and will make recommendations to HHS to address those concerns. The first issue that the Panel will be asked to review is the scientific evidence related to the theory suggesting an association of autism with vaccines. Also, factors to be considered by the Panel include: (1) the plausibility of the potential biologic association between a vaccine and the development of an unrelated disease or subsequent disorder, (2) the strength of the evidence for a causal relationship, and (3) the strength of the evidence for alternative hypotheses that might explain the occurrence of the condition or disease. In addition, the Panel is expected to identify the most pressing research needs associated with each concern addressed.

Because this will be an independent review process, IOM will select the panel members according to the established procedures used by IOM for constituting their expert panels. I am, therefore, unable to provide you with the names, resumes, and conflict of interest forms of prospective panel members. We understand, however, that following IOM's approval of committee members, there is a 20-day period for public comments on the committee's membership. Similarly, HHS is unable to provide an implementation plan and time-line for the IOM panel because the contract is still under negotiation. Once the contract is in place, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) will be available to update you on the panel's progress at your request.

In addition to undertaking the IOM review, CDC and NIH are currently exploring approaches to obtaining and evaluating biologic samples for a collaborative study of MMR vaccine relative to autism. They have contacted Dr. Ian Lipkin, an independent researcher from the University of California, Irvine, and have held preliminary discussions with IOM about overseeing such a collaborative project. Similarly, CDC is in discussion with Dr. A. J. Wakefield of the

Department of Medicine, University College London, as to the best approach to collaborating on an assessment of available data and findings relative to MMR vaccine and autism. I am hopeful that these discussions will result in mutually acceptable decisions.

In the meantime, through a cooperative agreement, CDC provided funding for the American Academy of Pediatrics (AAP) to hold a conference on autism and vaccines entitled "New Challenges in Childhood Immunizations." The conference was held in Chicago, Illinois, on June 12-13, 2000. There were approximately 75 participants, including facilitators, conference speakers, writing panel members, and AAP district representatives. In addition, the meeting was open to the public and the media. The writing panel for the conference consists of nine pediatricians and is chaired by Drs. Neal Halsey, Johns Hopkins University, and Susan Hyman, University of Rochester. The panel is reviewing the information presented and will draw conclusions about the proposed association between autism and certain vaccines that could be supported by current evidence and will make recommendations about additional research needs. The writing panel is scheduled to publish their report in the October 2000 issue of *Pediatrics*. We will provide a copy of the report to you once it is available.

Thank you for your interest in this important public health issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Donna E. Shalala". The signature is fluid and cursive, with the first name "Donna" being more prominent.

Donna E. Shalala